

a' contd  
Sub contd  
feeding with said feed an effective amount of a  $1\alpha$ -hydroxylated vitamin D compound for increasing phosphorus uptake in the cow's gut.

REMARKS

In the Office Action dated July 17, 2001, claims 1-7 were examined with the result that all claims were rejected. In response, Applicant has rewritten claim 1. In view of the above amendments and following remarks, reconsideration of this application is requested.

In the Office Action, claims 1 and 4-6 were rejected under 35 USC §102(b) as being anticipated by DeLuca et al U.S. Patent 4,338,312. It is the Examiner's position that the '312 reference teaches the administration of  $1\alpha$ -hydroxylated vitamin D compounds together with a low phosphorus diet for use in preventing parturient paresis (milk fever) in dairy cattle. As such, the Examiner believes the '312 reference inherently teaches the method claimed in the present application. Applicant, however, respectfully disagrees for the following reasons.

The DeLuca et al '312 patent discusses the feeding of a high calcium and low phosphorus diet to Holstein cows "in the dry period" and throughout the parturition portion of the experiment. Upon successful calving, the "treatment was discontinued." The Examiner is referred to the Example at column 3, lines 15-26. Thus, in the '312 patent, the  $1\alpha$ -hydroxylated vitamin D compound was given to the cow immediately prior to and during calving, i.e. what is referred to as the "dry period" of dairy cows. During this dry period the dairy cows are not lactating and are thus not producing milk. As a result, it would not be possible to determine whether the  $1\alpha$ -hydroxylated vitamin D compound given in the experiment of the '312 patent would "maintain milk production" since there is no milk production in the period in which the compound was administered to the cow. Clearly, the teaching in DeLuca et al '312 cannot inherently teach what

Applicant is claiming in the present application since there is no milk production during the "dry period" of dairy cattle. Thus, DeLuca et al '312 cannot anticipate the claimed invention. Further, the '312 reference cannot render the presently claimed invention obvious since there is no suggestion to one skilled in the art that the administration of  $1\alpha$ -hydroxylated vitamin D compounds would maintain milk production in a dairy cow since clearly the experiments set forth in the '312 reference are during the dry period of dairy cows and no milk production is occurring.

In order to emphasize this distinction, Applicant has amended claim 1 to now specifically state that the feed and the  $1\alpha$ -hydroxylated vitamin D compound is fed to a "lactating" dairy cow. Support for this amendment can be found in the specification as filed at page 11, lines 1-9. There is clearly no teaching of this method in the '312 reference, and there is no suggestion of the same since the cows are not lactating in the experiments set forth in the '312 reference.

In addition, it should be noted that the "low phosphorus" diet fed to the Holstein cows in the '312 reference contains approximately 0.5% phosphorus. A normal diet contains about 0.9% phosphorus. This 0.5% phosphorus diet was intentionally fed to the Holstein cows in order to induce milk fever disease to determine whether or not the administration of a combination of  $1\alpha$ -hydroxyvitamin D<sub>3</sub> and 25-hydroxyvitamin D<sub>3</sub> would prevent the disease. In contrast, Applicant's claim 1 calls for less than 0.3% phosphorus. This is a significant drop from even the "low phosphorus" feed utilized in the '312 reference. Thus, there is no suggestion to use such a low phosphorus diet as part of the daily feed to lactating cows.

In the Office Action, claims 1, 4-5 and 7 were rejected under 35 USC §102(b) as being anticipated by DeLuca et al U.S. Patent 4,110,446. The Examiner once again refers to the administration of  $1\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> and the treatment of milk fever disease in dairy cattle in the '446 patent, and concludes that Applicant's claimed method is inherent therein.

In response, and for the same reasons noted above, it is clear that the '446 reference is once again referring to the "dry period" of dairy cows. As the Examiner can see, the solution of 1,25-dihydroxyvitamin D<sub>3</sub> was given to dairy cows about 5 days prior to predicted calving. See column 4, lines 2-16. The '446 reference concludes at column 5, lines 10-17 that treatment with 1,25-dihydroxyvitamin D<sub>3</sub> is particularly effective during the critical period from about 24 hours pre- to 48 post-calving to prevent milk fever disease. Thus, it is clear that the compound 1,25-dihydroxyvitamin D<sub>3</sub> is not being administered during the lactation period of dairy cows. Instead, it is being administered immediately prior to calving and during the dry period of dairy cows.

Further, it should be noted that the dairy cows received a diet containing greater than 100g calcium and less than 45g phosphorus daily (see column 4, lines 9-12). A diet containing about 45g of phosphorus is not a "low phosphorus diet", and is clearly not one which would suggest a diet containing less than 0.3% phosphorus as claimed by Applicant. Thus, Applicant believes that the '446 reference does not anticipate or render obvious Applicant's claims.

In the Office Action, claims 2 and 3 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al '312 and DeLuca et al '446. Applicant believes, however, that neither of these references anticipate or render obvious claim 1, as now amended, and discussed above. As a result, Applicant believes claims 2 and 3 are allowable together with claims 1 and 4-7 in view of the above comments.

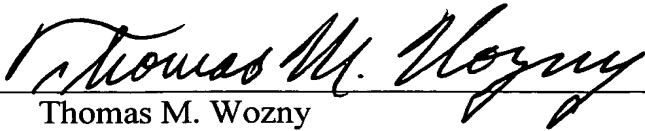
Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Application No. 09/815,573

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 has been rewritten as follows

1. (Amended) A method of maintaining milk production in a dairy cow fed a low phosphorus diet, comprising the steps of:

feeding a feed that contains about 0.3% by weight or less of an inorganic phosphorus supplement to a lactating dairy cow; and

feeding with said feed an effective amount of a  $1\alpha$ -hydroxylated vitamin D compound for increasing phosphorus uptake in the cow's gut.

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